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AUG - 8 1996

510(k) Summary
Flower™ Infusion Catheter

General Information

Trade Name:	*Flower*™ Infusion Catheter
Classification Name:	Catheter, Percutaneous
Classification:	Class II
Submitted By:	Interventional Innovations Corp. 2670 Patton Road St. Paul, MN 55113 (612) 636-6634
Contact:	Karen Peterson Director of Clinical and Regulatory Affairs
Predicate Device:	FasTRACKER® Infusion Catheter Target Therapeutics

Device Description

The *Flower*™ Infusion Catheter is a multi-lumen, over-the-wire device designed to locally deliver fluids into the peripheral vasculature.

Intended Use

The *Flower*™ Infusion Catheter is indicated for the delivery of therapeutic agents into the peripheral vasculature. It is not indicated for use in coronary or cerebral vasculature. It is not intended for use with thrombolytics. It is not intended for use with power injection pumps.

Testing

Physical testing of the product under simulated conditions included: dimensional inspection, deployment and recoil verification, marker band attachment, infusion flow rate, internal pressurization, bond strength, flexural fatigue strength, radial force, trackability, and guide catheter compatibility. All testing results were within product engineering and marketing specifications.

Biocompatibility testing was performed on the sterile materials used in the construction of these infusion catheters. All materials passed the biocompatibility testing and are suitable for this application.

Animal testing was conducted to assess placement of the device in a vessel as well as thrombus accumulation on the device. All results were satisfactory.

Summary of Substantial Equivalence

The *Flower*™ Infusion Catheter is constructed of the same or substantially equivalent materials to the predicate device. The sizes and configurations available along with the packaging and sterilization methods are also equivalent. The clinical indications for use are substantially equivalent to those of the predicate device. Because of the similarities in materials, construction, indications for use, packaging and testing results, this product does not raise any new safety or effectiveness issues.